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NOVARTIS

February 11, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Docket No. 1798N-036L, RIN0910-AA01** Laxative Drug Products for Over-the-Counter Human Use

Dear Sir/Madam:

On October 22, 2003, the Food and Drug Administration (FDA) announced a reopening of the administrative record for "Laxative Drug Products for Over-the Counter Human Use."

On January 20, 2004, The Consumer Healthcare Products Association submitted comments pertaining to the previously raised issue of allowable statements of identity (SOI) for over-the-counter OTC bulk-forming drug products. These comments are being submitted in response to the specific issues discussed in that letter. Novartis Consumer Health, Inc. (NCH) is a member company of the CHPA, however in this case are in firm opposition to the comments submitted by the trade association. NCH is the OTC division of Novartis Pharmaceuticals Corporation.

In their January 20, 2004 letter, CHPA refers to a letter from William E. Gilbertson, FDA, to William Soller, NDMA (Nonprescription Drug Manufacturers Association, the prior name of CHPA) on June 10, 1993. In that letter, FDA states "terms such as bulk-forming laxative" or "fiber laxative" when used as statements of identity would not require such clinical proof because these terms do not imply prevention or long term correction of disease. This sentence indicates FDA's intent to allow "fiber laxative" as a substitute for "bulk-forming laxative" when the monograph finalizes. NCH does not agree that "fiber laxative" constitutes an appropriate SOI as it does not meet the intent of a SOI.

As per 21CFR201.61 (b) "Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. Further, in response to comment 23 in the 1/15/85 TFM, the agency states, "laxatives relieve constipation by various actions, depending on how a specific ingredient works in the bowel. The identity statements...describe in nontechnical terms the effect a particular laxative product will have in the bowel or on the stool. Such information is necessary to provide consumers with adequate directions for using OTC laxative products safely and effectively..."

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NCH does not believe allowing "fiber laxative" as a statement of identity would provide consumers with a clear description of the anticipated action of the product. "Fiber" is a noun and does not have connotations of therapeutic action associated directly with it. "Fiber" does not have the same pharmacologic connotations as "bulk-forming" especially in light of the current state of science. There are many fibers which do not exert bulk-forming actions (e.g., inulins) and thus the term "fiber laxative" is not an accurate description. To look more closely at the terms:

From the January 15, 1985 TFM, the agency endorsed The Panel's original definition of a **bulk-forming laxative** as "an agent that promotes the evacuation of the bowel by increasing bulk volume and water content of the stools" in response to comment 32.

The definition of "fiber" is substantially different. In the 2001 Institute of Medicine Food and Nutrition Report by the Panel of the Definition of Dietary Fiber and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, the Panel proposed two definitions "to encompass current and future nondigestible carbohydrates in the food supply that are considered to be meaningful subdivisions of the potential substances that could be included". They proposed:

1. *Dietary Fiber* consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.
2. *Added Fiber* consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans

Total Fiber is the sum of *Dietary Fiber* and *Added Fiber*

This two-prong approach to define edible, nondigestible carbohydrates recognizes the diversity of carbohydrates in the human food supply that are not digested: plant cell wall and storage carbohydrates that predominate in foods, carbohydrates contributed by animal foods, and isolated and low molecular weight carbohydrates that occur naturally or have been synthesized or otherwise manufactured. These definitions recognize a continuum of carbohydrates and allow for flexibility to incorporate new fiber sources developed in the future following demonstration of beneficial physiological effects in humans.

NCH does not believe the terms 'bulk-forming" and "fiber" should be used interchangeably. Bulk-forming fibers may be a subdivision of all fibers, but as is clearly recognized by the scientific community, all fibers are not "bulk-forming". All fibers do not promote the evacuation of the bowel by increasing bulk volume and water content of the stools. NCH hopes the agency will consider the current state of the definition of fiber and keeps with providing the consumer with a description of the drug's action when considering the proposed change in the SOI.

To complicate matters further, 21CFR101.9 establishes a DRV (daily recommended value) for fiber intake at 25 grams per day (based on a caloric intake of 2,000 calories). If the SOI is established as "fiber laxative", the label declaration that the product is a source of "fiber" triggers the need for "supplement facts" labeling as outlined in 21CFR101.9.

The second point raised in the January 20, 2004 CHPA letter to the docket requests clarification of the "last substantive paragraph of FDA's 1993 letter which apparently contains an error. It says '...However, we might consider including the term 'fiber laxative' as an optional (allowable) indication for bulk-forming laxatives in the final monograph as follows: 'Fiber therapy for relief of occasional constipation' [which may be followed by '(irregularity)']. Evidently the term 'fiber laxative' was used where the term 'fiber therapy' was intended." NCH does not agree with CHPA's interpretation of the error. NCH believes FDA intended to write "fiber laxative" and used "fiber therapy" in error. This interpretation is clearly supported by the remainder of the 1993 letter, specifically where FDA states, "The term 'fiber therapy for irregularity' implies that the drug corrects, avoids, or prevents irregularity; in our view, such claims would require the submission of clinical studies."

NCH does not believe that the term "therapy" should be allowed and supports FDA's 1993 letter to NDMA. We agree with FDA that "therapy" implies long-term use which is clearly contraindicated by the "warnings" section of all laxative labels. Long term use of any laxative drug product should be under the care and supervision of a physician and labeling should not imply the consumer should initiate laxative "therapy" on their own.

NCH understands the docket is now closed, however we ask that the commissioner consider whether or not there is due cause to consider these comments since the letter being oppossed was submitted on the docket closing date of January 20, 2004. Should the FDA not consider these comments and chooses to include "fiber laxative" and/or "fiber therapy (or laxative) for relief of occasional constipation" as acceptable via the FM, we would ask that this letter be considered a petition to amend the monograph.

Should you need other information regarding this submission, please contact the undersigned at (973) 503-7791.

Respectfully submitted,
Novartis Consumer Health, Inc.,

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